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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/963,878	09/26/2001	Bruce S. Ellingboe	CV-0290US	9174

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06/25/2003

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EXAMINER

DEAK, LESLIE R

ART UNIT PAPER NUMBER

3762

DATE MAILED: 06/25/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/963,878

Applicant(s)

ELLINGBOE ET AL.

Examiner

Leslie R. Deak

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 September 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-101 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-101 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-20, 25-27, and 33-36, drawn to a perfusion system with a pump, classified in class 604, subclass 6.11.
 - II. Claims 21-24, drawn to a perfusion system with an oxygenator, classified in class 604, subclass 6.14.
 - III. Claims 28-32, drawn to a perfusion system with reservoirs and condition responsive sensors, classified in class 604, subclass 65.
 - IV. Claims 37-40, 68-69, drawn to a perfusion system with a cartridge, classified in class 417, subclass 477.2.
 - V. Claims 41-67 and 70-77, drawn to a perfusion system with an assembly, control unit and user interface, classified in class 604, subclass 5.01.
 - VI. Claims 86-87, drawn to a perfusion system with a filter and a heat exchanger, classified in class 604, subclasses 6.09 and 6.13.
 - VII. Claims 88-92, drawn to a method for maintaining a blood level in a perfusion system, classified in class 604, subclass 4.01.
 - VIII. Claims 93-96, drawn to a method of preventing bubble return to the patient, classified in class 604, subclass 6.09.
 - IX. Claims 97-99, drawn to a method of priming a pump circuit, classified in class 417, subclass 199.2.

- X. Claims 100 and 101, drawn to a method for testing for leaks in a pumping system, classified in class 417, subclass 14.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions in Groups I through VI are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct from each other if they are shown to be separately usable. In the instant case, each invention has a different element that may be used in a single perfusion system. Group I has separate utility such as use in a system that does not require oxygenation. Group II has separate utility such as use in a system that does not require heat exchange or reservoirs. Group III has separate utility such as use in a system that does not require oxygenation or heat exchange. Group IV has separate utility such as use in a system that does not require reservoirs, oxygenation, heat exchange, or flow control. Group V has separate utility such as use in a system that does not require heat exchange or oxygenation. Group VI has separate utility such as use in a system that requires filtration. See MPEP § 806.05(d).
3. Inventions in Groups I-VI and VII-VIII are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case both the method of maintaining a blood level in a perfusion system and preventing bubble return to the patient can be practiced by hand wherein an individual monitors the blood level and bubbles in the system visually.

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4. Inventions in Groups I-VI and IX-X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are a system for blood treatment and methods for priming and testing a pumping system. The claimed method in Groups IX and X does not recite blood withdrawal and return to the patient, may be practiced on any pumping system, and are therefore unrelated to the apparatus and method for blood treatment.

5. Inventions in Groups VII-VIII and IX-X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). Inventions in the above mentioned groups are different methods and are therefore independent and distinct.

6. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

7. This application contains claims directed to the following patentably distinct species of the claimed invention:

- a. Group I:
 - i. Species A: Claims 1-12, with fluid passageways and a single pump
 - ii. Species B: Claims 13-20, lacking fluid passageways but including two pumps

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- iii. Species C: Claims 25-27, lacking fluid passageways, but including two pumps and two pressure sensors
- iv. Species D: Claims 33-36, with fluid passageways and two pumps
- b. Group IV:
 - v. Species E: Claims 37-40, cartridge with tubing and a control unit
 - vi. Species F: Claims 68-69, cartridge with tubing, control unit, user interface, and display
- c. Group V:
 - vii. Species G: Claims 41-50, assembly with fluid circuit, control unit, flow controller, and user interface
 - viii. Species H: Claims 51-57, assembly with fluid circuit, control unit, user interface,
 - ix. Species I: Claims 58-67, assembly with fluid circuit, control unit, user interface, and 1st, 2nd, and 3rd display areas
 - x. Species J: Claims 70-74, assembly with fluid circuit, control unit, flow controller, sensor, and user interface
 - xi. Species K: Claims 75-77, assembly with control unit and user interface
- d. Group X:
 - xii. Species L: Claim 100, method of testing for leaks
 - xiii. Species M: Claim 101, method of testing for leaks, including a suction line

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, only claim 75 of Group V is held to be generic, for Group V only. None of the other claims are held to be generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

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8. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

9. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie R. Deak whose telephone number is 703-305-0200. The examiner can normally be reached on M-F 7:30-5:00, every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 703-308-5181. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3590 for regular communications and 703-305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0873.


Ira
June 17, 2003



**ANGELA D. SYKES
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700**